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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/031,774	08/26/2002	Andrew W. Heath	H0664/7003	8375
23628	7590	03/26/2004	EXAMINER	
WOLF GREENFIELD & SACKS, PC FEDERAL RESERVE PLAZA 600 ATLANTIC AVENUE BOSTON, MA 02210-2211			NGUYEN, QUANG	
			ART UNIT	PAPER NUMBER
			1636	

DATE MAILED: 03/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

8M.

Office Action Summary

Application No.

10/031,774

Applicant(s)

HEATH, ANDREW W.

Examiner

Quang Nguyen, Ph.D.

Art Unit

1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-20 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Amended claims 1-20 are pending in the present application, and they are subjected to the following restrictions.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 1-15, drawn to a method for the manufacture of a tissue composition or a medicament for use in tissue engineering, comprising transfecting a cell or tissue with a nucleic acid molecule encoding CD154, and an *in vitro* method to transfect a selected cell/tissue which does not naturally express CD154.

Group II, claim 16, drawn to an organ comprising at least one cell that has been transfected with a vector expressing CD154, wherein said cell does not naturally express CD154.

Group III, claims 18-19, drawn to a therapeutic vehicle comprising a cell that has been transfected with a nucleic acid molecule encoding CD154, wherein said cell does not naturally express CD154.

Group IV, claim 20, drawn to a cosmetic vehicle comprising a cell that has been transfected with a nucleic acid molecule encoding CD154, wherein said cell does not naturally express CD154.

The technical feature linking Groups I to IV appear to be that they all relate to a cell that has been transfected with a nucleic acid molecule encoding CD154, wherein the cell does not naturally express CD154.

However, Kipps et al. (WO 98/26061; IDS) already teach expression vectors containing accessory molecule ligand genes, including a gene encoding CD40 ligand or CD154; and methods for introducing these genes into desired cells including muscle cells, skin cells, stromal cells, connective tissue cells, fibroblasts as well as antigen presenting cells such as monocytes, macrophages, Langerhans cells, Kupffer cells (See Summary of the Invention, particularly page 11, lines 1-5, page 10, lines 24-27; page 15, line 21).

Therefore, the technical feature linking the inventions of Groups I to IV does not constitute a special technical feature as defined by PCT Rule 13.2, as it does not differentiate the claimed subject matter as a whole over the prior art. Since according to Rule 13.2 PCT the presence of such a common or corresponding special technical feature is an absolute prerequisite for unity to be established, and given that there does not appear to be any other technical feature common to the claimed subject matter as a whole which might be able to fulfill this role, the currently claimed subject matter lacks unity of invention according to Rule 13.1 PCT.

Consequently, the claimed subject matter is restricted into the aforementioned Groups of Inventions. The inventions are distinct, each from the other for the following reasons.

The organ of Group II, the therapeutic vehicle of Group III, the cosmetic vehicle of Group IV and a transfected cell or tissue prepared by the methods of Group I are physically and chemically different compositions, one from the others. It is further noted that the method for the manufacturing of a tissue composition or a medicament of

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Group I is not required to make an organ of Group II, nor a therapeutic vehicle of Group III nor a cosmetic vehicle of Group IV.

Because the currently claimed subject matter lacks unity according to Rule 13.1 PCT, and the inventions are distinct for the reasons set forth above, restriction for examination purposes as indicated is proper.

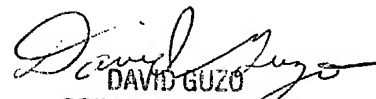
Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Quang Nguyen, Ph.D., whose telephone number is (571) 272-0776.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's mentor, David Guzo, Ph.D., may be reached at (571) 272-0767, or SPE, Irem Yucel, Ph.D., at (571) 272-0781.

To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1636; Central Fax No. (703) 872-9306.

Quang Nguyen, Ph.D.


DAVID GUZO
PRIMARY EXAMINER